



# To Take Or Not To Take: Bioethical Conflicts with Non-adherence to Medications due to Religious Beliefs

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***To Take Or Not To Take:  
Bioethical Conflicts with Non-adherence to Medications due to  
Religious Beliefs***

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Class of 2010

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*This paper is submitted in satisfaction of the course requirement*

**Abstract:**

The physician-patient relationship has continued to face problems set by the imbalance in the informed consent. Due to lack of informed dialogue, greater cultural competency and awareness, this issue is evident even today with the vast discrepancy that exists in the prescription process of medications and the non-adherence of patients with different religious backgrounds. Several physicians believe it is essential to have at least a minimal level of knowledge about various religious sensitivities so that negative impact on compliance is prevented. Many religious groups such as the Orthodox Christians, Muslims, Jews and Seventh Day Adventists have dietary restrictions that prevent them from taking some medications due to various ingredients in them. Much customer behavior is influenced by religion.

If physicians give their patients the alternative of taking medications other than the ones with such contents, then the patients would be better able to determine their own modes of treatment. However, if physicians take such measures, it is important to note that medications must then clearly state their ingredients. The history of labeling has been one of many lengthy procedures and time span. However, goals were set, achieved, and implemented although it took a long time. Similarly, if measures are taken to set goals to provide better alternatives of medications for patients with special dietary restrictions, the inequity in prescription and compliance would narrow.

## Introduction:

Since the formalized introduction of Medical Ethics in 1803, the physician-patient relationship has continued to face problems set by the imbalance in the informed consent. Some of these problems were exacerbated by the laws enacted during approval processes of drugs and their labeling. Due to tragedies like the elixir incident of 1937, physicians gained more authority giving patients even less freedom and autonomy to develop a more informed dialogue with their doctors and get complete thorough care. Due to lack of informed dialogue, greater cultural competency and awareness, this issue is evident even today with the vast discrepancy that exists in the prescription process of medications and the non-adherence of patients with different religious backgrounds.

Several cases have been reported where patients from various religious backgrounds, including Muslims, Orthodox Christians, and Seventh Day Adventists, have discontinued medications due to inert medication ingredients such as pork or beef gelatin and or stearic acid, which led to the relapse of their diseases<sup>1</sup>. Gelatin is one of the most controversial ingredients amongst the Jewish and Muslim communities. It is a protein obtained from animal (usually cows or pigs) tissues such as bone and skin. The gelatin content information is usually available in medication reference texts and from pharmaceutical manufacturers<sup>2</sup>. The relapse of diseases due to this discontinuation makes it a matter that can not be ignored. Several physicians believe it is essential to have at least a minimal level of knowledge about various religious sensitivities so that negative impact on compliance is prevented.

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<sup>1</sup> Sattar, S.P. *The Annals of Pharmacotherapy*. 2004; Vol. 38, No. 4, pp. 621-624.

<sup>2</sup> Pinals, D and Sattar, S.P. *Psychiatric Services*. 2002 Vol. 53 No. 2

For example, Jehovah Witnesses refrain from taking blood derived products<sup>3</sup> and Jewish patients avoid oral medications containing products such as glycerol, stearates, lactose and porcine<sup>4</sup>. Muslim patients refrain from taking medications with pork or alcohol contents. Thus medications containing lard, gelatin (unless beef specified), non-soy lecithin, and alcohol are all ingredients in products that Muslims refrain from using<sup>5</sup>. If religious prohibitions due to certain inert products are one of the many reasons for non-compliance to medication in patients, then it would be interesting to discover if such gaps in prescription and adherence could be narrowed with a more thorough approach to informed consent and better labeling of these products in prescription medications.

For example, it has been found that much of customer behavior is influenced by religion. When Dannon yogurt first obtained Kosher certification, sales increased approximately 25% amongst the Jewish population in the United States<sup>6</sup>. Furthermore, another study showed that although patients give preference to quality of doctors and hygiene of the hospital, a greater proportion chooses a hospital with a similar religious affiliation as the patient<sup>7</sup>. It may be inferred from such findings that one of the reasons for this choice is based upon a level of understanding patients feel physicians may have if they share a common religious faith or culture. It may be easier for a healthcare provider to deal with the patient if he or she understands the faith, values and culture of his or her patient. Another study showed that physicians achieved better and improved compliance with patients of Hispanic origin with psychotic disorders when recognition

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<sup>3</sup> Anon. Family care and medical management for Jehovah's witnesses. *Watch Tower*. Brooklyn, NY: Watch Tower Bible and Tract Society, 1995: 4-5.

<sup>4</sup> Spitzer J. *Caring for Jewish Patients*. Oxford: Radcliffe, 2003.

<sup>5</sup> Hammad, A. et al. ACCESS: Guide to Arab Culture: Health Care Delivery to the Arab American Community Community Health & Research Center Public Health Education and Research Department Series of Research Report No. -7-April, 1999

<sup>6</sup> Assadi, D. Do Religions Influence Customer Behavior? Confronting Religious Rules and Marketing Concepts. *Cahiers du CEREN*. 2003. pp. 2-13.

<sup>7</sup> Andeleeb, S.S. Religious Affiliation and Consumer Behavior. *Journal of Healthcare and Marketing*. 1993 Vol. 13, Issue 4.

of culturally based differences between patients and psychiatrists led to modifications in prescribing practices<sup>8</sup>.

An ethical conflict often arises for patients with such religious beliefs as there are over a thousand medications with either beef or pork derived gelatin or stearic acid products. A survey was designed for a pilot study consisting of 100 patients and physicians to assess their opinion about inert ingredients in medications that are restricted for individuals with various religious backgrounds. This study showed that 84% patients and 70% of the physicians did not know that several medications contained such products. Almost 63% of the patients and 70% of the physicians found it extremely important for the physician to inform their patients about such inert ingredients being present in the prescribed medication<sup>9</sup>.

One of the solutions suggested for such issues is the use of search engines such as the British National Formulary (BNF), which provides UK healthcare professionals with authoritative and practical information on the selection and clinical use of medicines. This engine can be easily used by physicians to find out which medications are derived from blood, alcohol, or any other animal derivatives<sup>10</sup>. Furthermore, it has been suggested to keep electronic records of patients so there can be 'prescribing alerts' available for patients with religious restrictions on medication products, thereby increasing the level of awareness about such issues.

Also, recently there has been the emergence of a limited supply of Kosher (Jewish friendly) and Halal (Muslim friendly) certified hard and soft gel capsules available at competitive prices. Many manufactures have developed other alternatives such as the vegetarian

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<sup>8</sup> Opler, L.A. et al. Rethinking Medication Prescribing Practices in an Inner-City Hispanic Mental Health Clinic. *Journal of Psychiatric Practice*. 10(2):134-140, March 2004.

<sup>9</sup> Sattar, S.P. *The Annals of Pharmacotherapy*: 2004; Vol. 38, No. 11, pp. 1830-1835.

<sup>10</sup> Gatrad et al. *Archives of Disease in Childhood*.2005; 90: 983-984

capsules that are made with starch and cellulose instead<sup>11</sup>. There is also the Physician's Desk Reference (PDR), the 'Bible for prescription drugs', which is available as PDR health ([http://www.gettingwell.com/drug\\_info/](http://www.gettingwell.com/drug_info/)) and also includes information on over the-counter (OTC) drugs, herbal medications, and nutritional supplements. Generic and brand names are provided as well as the uses, side effects, contraindications, special warnings, food and drug interactions, and dosage of the drug. Each entry includes images of the medications for identification. However, not many patients or physicians are aware of such sites, references and supplies and unless the physician informs the patients of such alternatives, the patients might never know. Physician–patient partnerships are essential when choosing amongst various therapeutic options to maximize adherence. Mutual collaboration fosters greater patient satisfaction, reduces the risks of non-adherence, and improves patients' healthcare outcomes<sup>12</sup>.

All these questions lead back to the interaction and relationship of the physician and patient, where the skills and attitudes of the physician are just as essential as the treatment of the patient. In states such as Massachusetts, patients have the right to refuse medication if they are deemed competent to make decisions<sup>13</sup>. The cases and studies show that patients refused medication based upon cultural and religious restrictions. With such freedom available to patients, a look into the history of informed consent is necessary to find out why this problem arises the way it does at this time.

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<sup>11</sup> Regenstein, J.M., et al. Kosher and Halal in the Biotechnology Era. *Applied Biotechnology, Food Science and Policy* 2003;1(2) 95–107

<sup>12</sup> Martin, L.R. et al. The Challenge of Patient Adherence. *Therapeutics and Clinical Risk Management*. 2005: 1(3) pp. 189-199

<sup>13</sup> Rogers v Commissioner of Mental Health 2995. Mass Supreme Court, 1983

## History of Informed Consent:

Throughout history the relationship between the physician and patient has been evolving alongside the shifting role of authority between the physician and patient. The historical roots of medical paternalism and non-disclosure to patients in Western Medicine was set early by the Greek Hippocratic oath where due to the impotence of the doctors, little was offered to patients except kind words. Despite the many recent judicial efforts to give patients a greater voice through the doctrine of informed consent historically, the doctor-patient relationship has been based on a one-way trust. Although a fair amount of knowledge is available about the codes of medical ethics and practice and the physician-patient relationship in ancient civilizations, there is little evidence that the formalized practice of legally binding informed medical consent existed before the late 19th century<sup>14</sup>.

In 1786, Benjamin Rush, one of the most celebrated physicians of the United States, a writer, educator, and humanitarian stressed the importance of the physician maintaining unyielding authority and only complying with patients when matters were of little importance. He gave great value to the education of the physician and patient to the level where the patient could comprehend and agree with the physician's recommendations. He honored the belief in the virtue of silent care and patient compliance. This was the type of relationship that Jay Katz termed as the silent care where patient compliance was a necessity and where all the power was in the hands of the physicians with the patients playing the submissive role<sup>15</sup>.

Furthermore, in 1803, Thomas Percival introduced the term "medical ethics" where he began to view the behavior and interactions of the physician in the society in which he expressed

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<sup>14</sup> Faden, R.R, Beauchamp, TL. *A History of Informed Consent* Oxford University Press. 1986

<sup>15</sup> Katz, J. *The Silent World of Doctor and Patient*. 1984



no need of the physician to reveal the truth to the patient if it would prove fatal to him<sup>16</sup>. He considered disclosure to patients to be harmful and limited freedom of patients was exercised. Thomas Percival was an English physician who was one of the most influential medical ethicists. He published his *Medical Ethics; or, a Code of Institutes and Precepts Adapted to the Professional Conduct of Physicians and Surgeons* which followed the tradition set by the Hippocratic Oath. His code stressed the authority and independence of the physician and the responsibility of the physician to take care of the sick—giving the physician the control paternalistic role in the doctor-patient relationship.

In 1847, the American Medical Association adopted Thomas Percival's Medical Ethics and wrote and published its very first code of medical ethics<sup>17</sup>. This led the way for the development and awareness of informed consent. For example, landmark cases such as the *Schloendorff v. NY Hospital* case in 1914 stressed the importance of self determination from the adult patient of sound mind and therefore imposed the obligation of obtaining consent from patients<sup>18</sup>. Slowly the awareness of the need of greater patient autonomy was emerging but not enough to pave the way for an end to silent care.

During World War II, doctors in Nazi Germany were conducting horrifying research on prisoners in concentration camps. This research was done on involuntary participants who usually died as a result of the experiments. After the war, many of these doctors were tried at the Nuremberg trials for their crimes. The International community was shocked by the revelations of their research. Violations in informed consent in the Nuremberg Trials led to the development of the Nuremberg Code in 1947. The Nuremberg Code was the first transnational code of ethics used for researchers and subjects across the world and was used to set the stage for all the future

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<sup>16</sup> Jonsen, AR. *A Short History of Medical Ethics*. Oxford University Press.1999

<sup>17</sup> Faden, RR. Beauchamp, TL. *A History of Informed Consent* Oxford University Press. 1986

<sup>18</sup> *Schloendorff v. Society of New York Hospital* 105 N.E. 92. N.Y. 1914

trials<sup>19</sup>. This code placed great importance to the voluntary consent of the patient giving him or her the capacity to exercise some of his or her rights as free human beings. The 1950s and 1960s were the eras where there was the rising sense of responsibility of providing appropriate information to patients and informed consent became more prevalent.

Additionally, in response to the atrocities committed by doctors in the Nazi era, the World Medical Association, a collaboration of most national medical associations, passed the Declaration of Geneva in 1948 which required the physician to not use his expertise against the laws of humanities. Just three months after the adoption of this document, the United Nations General Assembly adopted another document, the Universal Declaration of Human Rights in 1948 that was aimed at providing security for the person. The following year, in October 1949, the Third General Assembly of the World Medical Association at London adopted the International Code of Medical Ethics of the World Medical Association<sup>20</sup> which required the physician to act only in the interest of the patient. This international code served as another bridge to expressing the importance of the relationship of the physician and patient and the importance of the physicians dealing with the patients honestly and accurately.

Furthermore, in 1957, the superior court in the city and county of San Francisco declared that the duty to disclose the risks of treatments and medications was not a new duty but an extension of the originally established duty to disclose information about the nature of treatment and consequences to the patients<sup>21</sup>. Thus, through these developments, the relationship of the physician and patient became more refined with the attempt of making the patient's consent more adequately informed.

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<sup>19</sup> Annas GJ, Grodin MA. The Nazi Doctors and the Nuremberg Code: human rights in human experimentation. New York: Oxford University Press, 1992: 3-11.

<sup>20</sup> World Medical Association Bulletin, vol. 1, no. 3, October 1949, pp.109-111

<sup>21</sup> Salgo v. Leland Stanford Jr. University Bd. Of Trustees 154 Cal.App.2d 560, 317 P.2d Cal.App. 1957

By the late 1960s and early 1970s, the emergence of the legal doctrine of informed consent led most physicians to recognize both a moral and legal duty to provide for informed consent for procedures. In 1972, the *Canterbury v. Spence* case presented an interesting scenario to the realm of informed consent. In this case, the ruling was that the patient's right to self-decision is only plausible if the patient has enough information about that matter to make an intellectual choice. Thus, this gave the patient some rights to his own determination in treatment<sup>22</sup>. If the patient in the 1970s was given the authority to determine his treatment after the physician's suggestion, then similarly this can be paralleled to the current issue of medications with culturally or religiously prohibited inert ingredients. The patients in the case study did take charge of their treatment by not complying with consuming medication that may be prohibited by religious or cultural laws. However, if physicians give their patients the alternative of taking medications other than the ones with such contents, then the patients would be better able to determine their own modes of treatment. However, if physicians take such measures, it is important to note that medications must then clearly state their ingredients.

### **History of Labeling:**

Another area of extreme importance that relates directly to the labeling of drugs is the history of food and drug administration and the concept of the pharmacy. The perception of the pharmacy was a relatively new science in the nineteenth and early twentieth centuries as before the twentieth century there was no direct federal regulation on drugs or other consumer products. There was not a method or means available that could protect the public from harmful drugs or make them aware of the contents of the drugs. Efforts to define drugs and determine purity contents and composition in them developed with the efforts by the US Pharmacopoeia

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<sup>22</sup> *Canterbury v. Spence*, 464 F.2d 772 (DC Cir. 1972)

(USP)<sup>23</sup>. The USP consisted of physicians and pharmacists, who joined efforts voluntarily to compile a listing of the chemical components of drugs as well as tests to investigate the purity of drugs. At the same time, the American Medical Association formed in 1848 and shortly after the American Pharmaceutical Association constituted in 1852. During this time, in 1862, President Lincoln appointed a chemist to serve in the Department of Agriculture. In 1883, Dr. Harvey W. Wiley became chief chemist for the Bureau of Chemistry. His campaigning efforts for a federal law were very powerful and immense, such that he is considered the father of the Pure Food and Drug Act. This was the beginning of the Bureau of Chemistry, the predecessor of the Food and Drug Administration (FDA). The pharmacists from such associations developed the National Formulary in 1888<sup>24</sup>.

However, the official recognition of the National Formulary came in 1906 when Upton Sinclair published the book *The Jungle* which described the unhygienic conditions existent in meat packaging. This book and others like Dr. Wiley promoted Congress to pass the Pure Food and Drugs Act of 1906 recognizing the US Pharmacopoeia and the National Formulary as an official standard in testing purity, testing and strengths of drugs<sup>25</sup>. This 1906 law also pertained to labeling of drugs where drugs were considered ‘misbranded’ if they contained items such as an alcohol, opium, morphine, and or cocaine.

The scientists of the Bureau of Chemistry became involved in this process by running tests to purify the drugs. Through this law, with the combination of the performance of tests by the Bureau of Chemistry, drug manufacturing improved as well as the recognition of the need to

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<sup>23</sup> Sonnedeker, G. The Founding Period of the U.S. Pharmacopoeia. *Pharm Hist.* 1994; 36(3):103-22.

<sup>24</sup> Sonnedeker, Glenn. 1970. Contribution of the Pharmaceutical Profession toward Controlling the Quality of Drugs in the Nineteenth Century. In *Safeguarding the Public: Historical Aspects of Medicinal Drug Control*, edited by J. B. Blake. Baltimore: Johns Hopkins University Press.

<sup>25</sup> Temin, Peter. 1980. *Taking Your Medicine: Drug Regulation in the United States*. Cambridge, Mass.: Harvard University Press

provide more information about drug contents. Furthermore, the Sherley Amendment of 1912 clearly banned fraud and deceitful claims about the contents of the drugs. During this time, the FDA's role as a monitoring agent in identifying drugs became affirmed. In 1927, the Bureau of Chemistry regrouped to become the Food, Drug, and Insecticide Administration, which in 1930 changed its name to the Food and Drug Administration<sup>26</sup>. Some of the specific functions of the FDA included regulating data on food labels, overseeing clinical trials for new drugs and investigating consumer complaints about food and drugs. The latter was extremely important as seen in the case of Massengel.

In 1937, Massengel, a pharmaceutical company of Bristol, Tennessee introduced a new drug with sulfanilamide, the first sulfa antimicrobial drug. In this drug diethylene glycol was used as the solvent in the formulation of a liquid preparation of sulfanilamide known as Elixir Sulfanilamide. This solvent diethylene glycol proved fatal for people and as a result hundreds of people, mostly children, died from an untested elixir<sup>27</sup>. The Elixir Sulfanilamide disaster of 1937 was one of the most consequential mass poisonings of the twentieth century. One hundred five patients died from its therapeutic use. Under the existing drug regulations, pre-marketing toxicity testing was not required<sup>28</sup>. This tragedy engendered the way for Congress to pass the 1938 Federal Food, Drug, and Cosmetic Act—regulatory legislation that for the first time required drug manufacturers to show drug safety before public sale and distribution. It remains the basic law today. The relationship between the pharmaceutical industry and the government and its effect on the practice of medicine were significantly changed by this event<sup>29</sup>.

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<sup>26</sup> Kleinfeld, Vincent A. 1970. Commentary and participation in Discussion. In *Safeguarding the Public: Historical Aspects of Medicinal Drug Control*, edited by J. B. Blake. Baltimore: Johns Hopkins University Press

<sup>27</sup> Krauss, Michael I. 1996. Loosening the FDA's Drug Certification Monopoly: Implications for Tort Law and Consumer Welfare. *George Mason Law Review* 4 (spring): 457–83.

<sup>28</sup> Wax, PM. Elixirs, diluents and the passage of the 1938 Federal Food, Drug and Cosmetic Act. *Ann Intern Med*. 1995 Mar 15;122(6):456-61.

<sup>29</sup> Jackson CO. Food and Drug Legislation in the New Deal. Princeton, NJ: Princeton University Press; 1970:151-74

The 1938 law mandated that all new drugs be tested and proven for safety before being released in the market. Formula disclosures of all active ingredients became a requirement. Directions on how to use the medications as well as the prescriptions of drugs were also required. It also banned dangerous drugs and misbranding of drugs as well<sup>30</sup>. Such strict regulations increased the practice of requiring prescriptions for certain drugs. This proved evolutionary in the way patients obtained medication. In turn, it engendered a change in the patient physician relationship as well. This occurred during the time when Durham-Humphrey Amendment in 1951, drew a concise legal distinction between prescription-only and over the counter (OTC) drugs, and authorized the FDA to classify drugs accordingly<sup>31</sup>. With this amendment, certain drugs could be prescribed only by doctors. This gave the role of the physician great authority as a patient's right to use to a specific drug was not accessible through money but required visitation to the doctor. This incident with the elixir drug had a multifaceted impact in general. It brought greater awareness of properly monitoring labeling of drugs yet it also caused an imbalance in the physician patient relationship as the dependence on the doctor was further legitimated by complicating the patient's right to gain information about the drugs by the labeling and advertising controls<sup>32</sup>. Thus, the freedom of the patient to self-medicate was violated due to events like the elixir incident which had left hundreds dead while monitoring controls on drugs before getting on market improved.

Although, great improvements were implemented through the 1938 law, drastic limitations in regulations still remained. Proof of the efficacy of drugs was not yet required,

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<sup>30</sup> Federal Food, Drug, and Cosmetic Act 1938. Public Law 717,52, Stat 1040; 25 June 1938.

<sup>31</sup> Wardell, W. M., and L. Lasagna. 1975. *Regulation and Drug Development*. Washington, D.C.: American Enterprise Institute for Public Policy Research.

<sup>32</sup> Young, James Harvey. 1970. Drugs and the 1906 Law. In *Safeguarding the Public: Historical Aspects of Medicinal Drug Control*, edited by J. B. Blake. Baltimore: Johns Hopkins University Press

human clinical trials were conducted poorly, drugs studied in pre-marketing clinical trial were not reviewed, and animal testing was not standardized<sup>33</sup>.

It took another twenty three years before any significant attempt was implemented to make drug safety regulations stronger. Despite the efforts of senators, another drug calamity like that of Elixir Sulfanilamide Disaster 1937 which left hundreds dead further emphasized and further continued reform in the regulation of drugs. During this period, it was the drug thalidomide that caused the tragedies. In 1962, a new sleeping pill called thalidomide was produced only to discover that it caused birth defects in thousands of babies in Western Europe. Due to the strict regulations set in 1938 and the role of Dr. Francis Kelsey, an FDA official who prevented this drug from getting on the market, thalidomide was prevented from causing disasters in the United States<sup>34</sup>.

However, despite this regulation, thalidomide was manufactured from a pharmaceutical company, Merrell Pharmaceutical and supplied to many physicians in the United States. Through this, thalidomide was distributed amongst 20,000 patients, including pregnant women<sup>35</sup>. This was a clear indication that more strict laws of regulation were still required to prevent such incidents from occurring. Thus, in 1962, more new Drug Amendments were passed to ensure drug efficacy and greater drug safety. These laws reduced the choices of the doctors and patients and expanded those of the FDA. The FDA was required to closely monitor drug development at all stages. Animal testing became a mandatory process before human trials were conducted and

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<sup>33</sup> Janssen WF. FDA since 1938: The major trends and developments. *Journal of Public Law*. 1964; 13:205-21.

<sup>34</sup> McFadyen RE. Thalidomide in America: a brush with tragedy. *Clio Med*. 1976; 11:79-93.

<sup>35</sup> Thalidomide. *Public Health Report*. 1962; 77:946

time limitations on drugs were removed<sup>36</sup>. Due to the removal of time limitations, drug developments in general lengthened.

In 1966, the Fair Packaging and Labeling Act was passed that required all consumer products to be honestly and informatively labeled on foods, drugs, cosmetics, and medical devices<sup>37</sup>. In 1970, the FDA required the first patient package insert. In 1972, this labeling was further promoted to be used for over the counter drugs when the FDA began reviewing these drugs for safety and effectiveness. With such lengthy procedures in regulations and approvals, it is hard to fathom how long it will take for the industry to come up with solutions of providing alternative drugs or improve labeling more efficiently for people with different cultural backgrounds and religious beliefs.

As years passed with such strict regulations, by the time it was the 1980s, the time spanned for drug approval reached almost twenty years<sup>38</sup>. This length posed a serious problem for the patients who were in dire need of those drugs for their conditions. Awareness of the patient's concerns led to a reform in the approval process. At the same time, in 1983, the Orphan Drug Act was also created to promote the development of drugs for rare diseases that affected a very small population of only under 200,000 people in the United States. Congress implemented this act to ensure that the products with low commercial value but useful in saving lives would also be produced in the market. To promote this act, tax breaks were provided and privileges were given to the companies that sponsored the production of such drugs<sup>39</sup>. Orphan drugs have

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<sup>36</sup> Schnee JE. Governmental control of therapeutic drugs: intent, impact and issues. In: Lindsay CM, Caglarcan E, eds. *The Pharmaceutical Industry: Economics, Performance, and Government Regulation*. New York: Wiley; 1978:9-14

<sup>37</sup> Meadows, M. Promoting Safe and Effective Drugs for 100 Years. *FDA Consumer Magazine*. Vol 40 (1) | January-February 2004

<sup>38</sup> Statman, Meir. 1983. *Competition in the Pharmaceutical Industry: The Declining Profitability of Drug Innovation*. Washington, D.C.: American Enterprise Institute for Public Policy Research.

<sup>39</sup> Haffner, M. Orphan Drug Development Update. *Drug Information Journal*, Vol. 30, pp. 29–34, 1996



continued to be produced since and have been immensely successful as well. It would be interesting to see what would happen if congress lobbied for a similar type of act that provided privileges and tax breaks for companies that developed alternative drugs specifically for people with specific religious and or culture beliefs. It could be that the way the Orphan Drug Act has remained successful, such an initiative might be successful as well and prevent relapse of diseases of many patients in the population.

Many other acts were passed during the 1980s such as the Waxman-Hatch Act of 1984 which protected time loss on patent drugs before generic ones could be produced and the Drug Export Amendment Act of 1986 that attempted to protect drug loss by preventing unapproved drugs from being exported. However, it was not until the 1990s that labeling contents became official. In 1990, the Nutritional Labeling and Education Act was passed<sup>40</sup>. Finally, labeling of nutritional products on most food products except meat and poultry were made a requirement after being illegal before the 1970s<sup>41</sup>. This was an integral step in building awareness of nutrient content in products. This act gave FDA authority to allow health claims on food products and dietary supplements which led to the passing of the Dietary Supplement Health and Education Act of 1994 by President Clinton<sup>42</sup>. This act helped ensure that safe and appropriately labeled products were available to those who wanted to use them.

To enable a more expedited review of drugs, the FDA Modernization Act of 1997 was passed<sup>43</sup>. Labeling for over the counter drugs became standardized in 1999 similar to the nutritional facts about foods. Furthermore, the sources of information on the inactive ingredients

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<sup>40</sup> <http://www.fda.gov/opacom/backgrounders/foodlabel/newlabel.html>

<sup>41</sup> Viscusi, W.K.1996. "Regulatory Reform and Liability for Pharmaceuticals and Medical Devices," *Advancing Medical Innovation: Health, Safety and the Role of Government in the 21st Century*, The Progress and Freedom Foundation, February 7, 1996: 79-102.

<sup>42</sup> Pinco, R. G & Rubin P.D. 1996. Ambiguities of the Dietary Supplement Health and Education Act of 1994. *Food and Drug Law Journal* 51: 383–405.

<sup>43</sup> <http://www.fda.gov/cdrh/modact/modern.html>

in drugs became available and got listed on the label of every over the counter drugs and in the package inserts which is now available from a pharmacy, PDR, and other websites for prescriptions drugs. In 2004, the Food Allergy Labeling and Consumer Protection Act was passed to protect consumers with food allergies such as with peanuts, tree nuts, soybeans, fish, and more<sup>44</sup>. Just recently in 2005, the formation of the Drug Safety Board took place with representatives from the National Institute of Health, FDA staff, and representatives from the veteran's association. This board will be used for protecting the safety of patients by providing more information about the drugs to health professionals and patients about drug safety issues and regulating drugs already on the market<sup>45</sup>.

The history of labeling has been one of many lengthy procedures and time span. However, goals were set, achieved, and implemented although it took a long time. Similarly, if measures are taken to set goals to provide better alternatives of medications for patients with special dietary restrictions, the inequity in prescription and compliance would narrow.

### **Discussion:**

The evolving relationship of the physician and patient has become stagnant due to multiple issues raised in the system today that have also been witnessed in the past. With tragedies like the elixir incident of 1937, physicians have gained more authority giving patients even less freedom and autonomy to develop a more informed dialogue with their doctors and get complete thorough care. This authority has created a gap in the system.

Thus, cultural competence, greater awareness of available drugs and their alternatives, a more informed dialogue between the patient and physician can foster a balance and assist in diminishing the gaps present in the current system. This balance between religious and clinical

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<sup>44</sup> [http://www.fda.gov/fdac/features/2006/106\\_fdawork.html](http://www.fda.gov/fdac/features/2006/106_fdawork.html)

<sup>45</sup> <http://www.newscientist.com/article.ns?id=dn7017>

needs is necessary. The respect for patient autonomy has a central role in the justification and function of informed consent requirements. Historically, landmark cases such as the *Schloendorff v. NY Hospital* case in 1914 have continuously emphasized the importance of self determination in patients. This emphasis has evolved into many areas that need greater attention such as that with patient adherence to medications.

However, how much is enough and how much should the clinician know to be able to provide the patient with the most appropriate treatment and inform him thoroughly about it?

How much information should be disclosed to the patient?

Lidz, Appelbaum, and Meisel suggest that the problems of informed consent root from the way informed consent is implemented. They suggest trying the process model which emphasizes active participation of the patient in medical decision-making<sup>46</sup>. This is somewhat similar to what Jay Katz described as the informed dialogue between the patient and physician where the patient is accepted as a valued member of the healthcare team, one who has choice and authority to play a role in the decisions.

Another report by Veatch has questioned if informed consent is even appropriate in the medical decision making process. This report has argued that it is impossible for physicians to come up with the appropriate treatment without active patient participation which mirrors the process model and the idea of informed dialogue. This report's contribution to informed consent is based on the idea that the patient physician relationship should be based on deep values where the healthcare systems reorganize around particular orientations such as Catholic, holistic, and more. This would make it easier for patients to choose physicians who understand their

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<sup>46</sup> Lidz CW, Appelbaum PS, Meisel A. "Two Models of Implementing Informed Consent." *Archives of Internal Medicine*, June 1988. Vol 148, 1385-1389

backgrounds and beliefs, and would thereby reduce the gap of nonadherence to medications and making the decision making process easier<sup>47</sup>. Although, ideally this would result in fewer misunderstandings between the unique relationship of the patient and physician, it is not always possible. General cultural competency, awareness of backgrounds could potentially be one of the keys to better patient compliance to medications.

Is it possible to control the inactive ingredients in drugs and get all the related information from the labeling of the drugs instead of dependence on the physician? Well for one, there are now sources of information on the inactive ingredients in drugs. They are listed on the label of every over the counter drug and are listed in every package insert—which is usually available from the pharmacy, PDR, or website—for prescription drugs. Similarly, in Australia, pharmaceutical manufacturers include in depth declarations in the drug packages about the source of materials used in the preparation of their drugs<sup>48</sup>. So in a way, patients do now have some more accessibility to obtaining information about the complete contents of their drugs. It may not be as obvious as people hope, but if efforts are made, and time is taken to read the inserts and call up the companies, they can eventually figure out what ingredients are in the drugs.

With regards to controlling the inactive ingredients in drugs, however, there are several issues with labeling that need to be taken into consideration. First, the FDA has no authority to require a drug company to not use a type of inactive ingredient unless the ingredient is safe.<sup>49</sup> Furthermore, the FDA cannot require that a pharmaceutical company distribute two or more types of drugs, with different inactive ingredients. With this set up, it is indeed unclear how many different types of inactive ingredients would have to be required in order to satisfy all of

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<sup>47</sup> Veatch RM. "Abandoning Informed Consent." *Hastings Center Report*, 1995. 25(2):5-12.

<sup>48</sup> Anesthesia for Vegetarians: Anesthesia. 2005 May;60(5):520-1

<sup>49</sup> <http://www.fda.gov/Drugs/InformationOnDrugs/ucm080123.htm>

the diverse religions and views of the United States. This would also pose various challenges if some religions were given priority over others in this matter. If somehow this process was encouraged and passed—as seen by the history of labeling of drugs, this process in itself would require many years before implementation would actually occur. After the passing of the 1938 Food Drug and Cosmetic Act, it took another twenty years before any other drug regulation was implemented. Similarly, it would not be surprising if such a huge gap occurs before FDA is ever granted this approval, although it is very unlikely that it is even possible.

Moreover, one of the reasons for this is because a drug manufacturer is not permitted to change inactive ingredients in a prescription drug or market two forms of the same drugs with inactive ingredients without extensive testing. This testing would cost millions of dollars and then obtaining FDA approval would take another long period of time. This would be very costly. It is hard to predict who would pay for this process. Even if the religious groups did decide to contribute to this, would this be something feasible and efficient to do? Is just having thorough label inserts enough? How can cultural or religious non adherence be prevented?

Although attempts have been made to end the silence in the patient and physician relationship throughout history, elements of silent care still remain, such as nonadherence to medications due to unawareness and lack of cultural competency. This demonstrates their detrimental effect on proper patient care.

With the advent of sophisticated technology playing an integral role in medical care, there is a greater need of informed dialogue to exist between patients and physicians. This is necessary so that physicians can respect the needs of the patient and the autonomy of the patient can be restored and true informed consent exercised—a system where patients and doctors can communicate more and the paternalistic role of the doctor is transferred into that of a friend—a

relationship of transference and counter transference. Purity in transference is needed to improve this relationship. This dialogue does not rest only between the patient and physician.

However, the rise of managed care organizations prevents doctors from giving full disclosure. Now even if a doctor wants to inform the patient thoroughly, time limiting factors prevent him from proper informed dialogue. The financial pressure placed on the doctors limits their willingness to understand the patient. The more time the doctors spend with one patient result in loss net income to the higher administration of the hospital. The more patients the doctors see, the higher the income. This also results in doctors being reluctant to view their patients in a holistic manner and restricts them to hold only the necessary conversation. Higher administration needs to be supportive of the doctors by giving them the flexibility to build a proper relationship.

This is also where the help of the pharmaceutical companies come in. In the age where electronic records are used and effective, innovative technology and methods could possibly be considered. If the FDA and or drug companies can somehow figure out an electronic system that can give alerts about ingredients for various religious groups, or provide alternative vegetarian drugs, and formulate ways to have medical information about the drugs more accessible to the public—such as in the form of drug advertisements to inform the patients and physicians of the contents—then maybe the problem of non compliance to medications due to inert ingredients can be prevented in the future. How feasible these ideas and methods are, one cannot predict but continuous awareness about this problem can help make strides in this issue.

In the near future, it would be interesting to find out if increasing awareness of this problem and finding a solution to this type of non-adherence to medication would increase public health awareness and the overall public health in various states.